

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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VS

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/188,442 11/09/98 ROURKE

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IM62/0217

EXAMINER

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TORRES VELAZQUEZ, N

ART UNIT PAPER NUMBER

1771

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DATE MAILED:

02/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/188,442	ROURKE ET AL.
Examiner	Art Unit	
Norca L. Torres-Velazquez	1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1) Responsive to communication(s) filed on 08 February 1999 .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) 17-20 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3, 5, 7-12, 15 and 16 is/are rejected.

7) Claim(s) 4, 6, 13 and 14 is/are objected to.

8) Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
a) All b) Some * c) None of the CERTIFIED copies of the priority documents have been:
1. received.
2. received in Application No. (Series Code / Serial Number) _____.
3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) Notice of References Cited (PTO-892) 17) Interview Summary (PTO-413) Paper No(s). _____
15) Notice of Draftsperson's Patent Drawing Review (PTO-948) 18) Notice of Informal Patent Application (PTO-152)
16) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 19) Other: _____

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-16, drawn to a product, classified in class 442, subclass 123.
 - II. Claims 17-20, drawn to a process of use, classified in class 604, subclass various subclasses. The inventions are distinct, each from the other because of the following reasons:
2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pre-moistened wipe can be used as a transdermal delivery system.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Julia A. Glazer on 2/8/2000 a provisional election was made with traverse to prosecute the invention of group I, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicant is reminded that upon the cancellation of claims to a non-

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elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8-9 and 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-9 and 15-16 are indefinite because they use a property to define the antimicrobial protease. *Ex parte SLOB*, 157 USPQ 172, “*Claims merely setting forth physical characteristics desired in article, and not setting forth specific compositions which would meet such characteristics, are invalid as vague, indefinite, and functional since they cover any conceivable combination of ingredients either presently existing or which might be discovered in future and which would impart desired characteristics.*”

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 1-3, 5, 7, 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over RICHARDS et al. (US Patent 5,629,081) in view of GRIFFIN et al. (US Patent 5,230,897).

RICHARDS et al. discloses a pre-moistened, dispersible, and biodegradable wet wipe comprising a web of non-woven fibers contacted with a PVOH binder. (Abstract) The non-woven fibers contacted with a PVOH binder will read on Claim 7 that requires a that the fibers of the wipe are chemically bonded together. RICHARDS et al. also teaches that the wet wipe contains aqueous lotion solution in ranges from 100 to 350 percent by weight of the web. (Column 8, lines 23-25), and also that the aqueous lotion comprising a preservative effective for inhibiting microbial activity. (Column 8, lines 15-20). The preservative generally comprises from about 0.01 to about 1.5 percent by weight of the lotion. (Column 5, lines 8-10). RICHARDS teaching reads on the ranges claimed in claim 1 since the percentage of liquid in the fiber ranges from 50%-800%.

RICHARDS et al. also teaches the use of a preservative system that provides anti-microbial activity and among the preferred preservatives is hexamidine [*which is incorrectly spelled as hexaminidine in the reference*]. (Column 4, line 60 – Column 5, line 5). However, the reference does not disclose that protease inhibitor is from the group consisting of pentamidine.

GRIFFIN et al. discloses a pharmaceutical composition for transdermal delivery of pentamidine. GRIFFIN et al. teaches that pentamidine is known to be an effective anti-protozoal and fungicidal agent. (Column 1, lines 13-14).

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Since RICHARDS et al. and GRIFFIN et al. are both from the same field of endeavor, the purpose disclosed by GRIFFIN et al. would have been recognized in the pertinent art of RICHARDS et al.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify RICHARDS et al. wet wipe to use pentamidine as a protease inhibitor for the treatment of protozoal and fungal diseases as disclosed by GRIFFIN et al. (Column 1, lines 36-37). The concentration of antimicrobial protease inhibitor and content of liquid in the fiber are considered to involve routine optimization while has been held to be within the level of ordinary skill in the art. As noted in *In re Aller*, the selection of reaction parameters such as temperature and concentration would have been obvious:

"Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely degree from the results of the prior art... such ranges are termed "critical ranges and the applicant has the burden of proving such criticality... More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

In re Aller 105 USPQ 233, 255 (CCPA 1955). See also *In re Waite* 77 USPQ 586 (CCPA 1948); *In re Scherl* 70 USPQ 204 (CCPA 1946); *In re Irmscher* 66 USPQ 314 (CCPA 1945); *In re Norman* 66 USPQ 308 (CCPA 1945); *In re Swenson* 56 USPQ 372 (CCPA 1942); *In re Sola* 25 USPQ 433 (CCPA 1935); *In re Dreyfus* 24 USPQ 52 (CCPA 1934).

Therefore, one of ordinary skilled in the art at the time the invention was made would have modified RICHARDS et al. by including from about 0.004% to 10% antimicrobial protease inhibitor in the substrate and from about 0.5 grams to 8 grams of liquid per gram of dry fiber in order to optimize the wipe.

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9. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over LUU et al. (US Patent 5,871,763) in view of GRIFFIN et al. (US Patent 5,230,897).

LUU et al. discloses a substrate treated with a lotion which, optionally, contains one or more of the following: a surfactant which aids in skin cleansing, and a medicinal agent, such as an antimicrobial agent which kills bacteria and fungi commonly found on skin. (Column 3, lines 1-6). LUU et al. also discloses the use of a wet-strengthened, or wipe or nonwoven material. (Column 3, line 10). The reference also teaches that an antibacterial agent can be present in an amount of from about 0.01% to about 10%, preferably from about 0.05% to about 5%, of the lotion. (Column 9, lines 29-31).

LUU et al. also discloses that the substrate can be any suitable applicator that the lotion can be retained upon. Suitable substrates include a web, gauze, cotton swab, transdermal patch, container or holder. (Column 13, lines 19-22). However, the reference does not disclose that protease inhibitor is from the group consisting of pentamidine.

GRIFFIN et al. discloses a pharmaceutical composition for transdermal delivery of pentamidine. GRIFFIN et al. teaches that pentamidine is known to be an effective anti-protozoal and fungicidal agent. (Column 1, lines 13-14).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify LUU et al.'s wet wipe to use pentamidine as a protease inhibitor for the treatment of protozoal and fungal diseases as disclosed by GRIFFIN et al. (Column 1, lines 36-37). The concentration of antimicrobial protease inhibitor and content of liquid in the fiber are considered to involve routine optimization while has been held to be within

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the level of ordinary skill in the art. As noted in *In re Aller*, the selection of reaction parameters such as temperature and concentration would have been obvious.

Therefore, one of ordinary skilled in the art at the time the invention was made would have modified LUU et al. by including from about 0.004% to 10% antimicrobial protease inhibitor in the substrate and from about 0.5 grams to 8 grams of liquid per gram of dry fiber in order to optimize the wipe.

Allowable Subject Matter

10. Claims 4, 6, 13-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art doesn't teach the use hexamidine diisethionate as an antimicrobial protease inhibitor in a premoistened wipe.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

VIANEN et al. (US Patent 5,945,110)

BAUER (US Patent 3,786,615)

KAJS et al. (US Patent 4,714,563)

MITRA et al. (US Patent 5,686,088)

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Norca L. Torres-Velazquez whose telephone number is 703-306-5714. The examiner can normally be reached on Monday-Thursday 7:30-5:00 pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 703-308-2414. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3599 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1495.

nlt *mk*
February 11, 2000



TERREL MORRIS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700